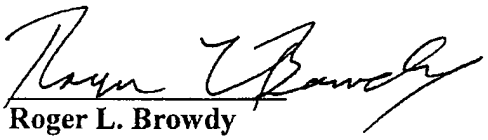
United States Court Of Appeals For The Federal Circuit

David Wallach et al.,	)	
	)	
Petitioner or Appellant,	)	
	)	**PETITION FOR REVIEW**
v.	)	
	)	
U.S. Patent and Trademark Office,	)	
	)	
Respondent or Appellee.	)	

David Wallach, Mark Boldin, Eugene Varfolomeev and Igor Mett hereby petition/appeal the court for review of the Decision on Appeal, in Appeal 2007-2228, of the Board of Patent Appeals and Interferences entered on November 15, 2007, in U.S. Patent Application No. 09/824,134, Confirmation No. 2547, filed April 3, 2001. The order or decision was received on November 19, 2007.

Respectfully submitted,

BROWDY AND NEIMARK, PLLC

By: 

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID WALLACH, MARK BOLDIN,
EUGENE VARFOLOMEEV, and IGOR METT

Appeal 2007-2228
Application 09/824,134
Technology Center 1600

Decided: November 15, 2007

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1-7, 11, and 14. We have jurisdiction under 35 U.S.C. § 6(b). Claim 1 is representative of the claims on appeal, and reads as follows:

1. An isolated DNA molecule comprising:

(1) a DNA sequence which encodes the MORT-1 protein, having the amino acid sequence of SEQ ID NO:2;

(2) a DNA sequence which encodes an analog of said MORT-1 protein, which analog binds with the intracellular domain of the FAS ligand receptor (FAS-IC), which DNA sequence is capable of hybridization to the cDNA encoding SEQ ID NO:2 under moderately stringent conditions; or

(3) a DNA coding sequence consisting of a DNA sequence which encodes a fragment of said MORT-1 protein which binds with FAS-IC.

We affirm.

DISCUSSION

Indefiniteness

Claims 1-7, 11, and 14 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Appellants regard as the invention. As Appellants do not argue claims 2-7, 11, and 14 separately from claim 1, they stand or fall with claim 1, and we focus our analysis on claim 1. 37 C.F.R. § 41.37(c)(1)(vii) (2006).

According to the Examiner:

> Claims 1-7, 11, 14 are indefinite, because claims 1-2 recite "moderately stringent hybridization conditions". Moderately stringent conditions are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree of moderately stringent conditions and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

(Answer 4.)

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification."

Miles Laboratories, Inc. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993). "[A]mbiguity in claim scope is at the heart of the definiteness requirement of 35 U.S.C. § 112, ¶ 2." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003). A "claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention." *Id.*

Appellants argue that at the time of invention, "the metes and bounds of moderate stringency were known to those of skill in the art, even though there may be some variation in the means for providing roughly the same level of stringency either at the hybridization stage or at the wash stage." (Br.[1] 11.) Appellants argue that "in view of the teachings of the prior art, it is urged that the claim interpretation to be given to the term 'hybridization under moderately stringent conditions' are those conditions which would permit detection of nucleotide sequences at least approximately 75% homologous." (*Id.* at 14.)

Appellants cite US Patent No. 5,026,636,[2] as defining moderate stringency "as conditions that allow detection of nucleotide sequences at least approximately 75% homologous to the probe." (*Id.* at 11). The '636 patent is also cited for teaching that moderately stringent conditions for a particular probe, "when seeking a specified degree of homology," may be determined by those skilled in the art using the guidance provided by *Nucleic Acid Hybridisation: A Practical Approach* (Hames and Higgins, eds., IRL Press, Washington (1985)) and Wood ("Base composition-independent hybridization in tetramethylammonium chloride: A method for

[1] All references to the Brief (Br.) are to the Appeal Brief dated May 19, 2006.

[2] Baseman, US Patent No. 5,026,636, issued June 25, 1991.

oligonucleotide screening of highly complex gene libraries," *Proc. Natl Acad. Sci. USA*, Vol. 82, pp. 1585-1588 (1985)) (Br. 11-12). Appellants further cite *Current Protocols in Molecular Biology* (eds. Ausubel et al., John Wiley & Sons, Inc., (1987-1998)), as evidence that the skilled artisan would know how to use "a rational approach at determining 'moderate stringency' wash conditions by calculating the decrease in temperature required using the correlation for decrease in T_m, per percent mismatch." (Br. 14.)

Appellants also cite US Patent Nos. 4,968,607,[3] 5,171,675,[4] 5,198,342,[5] 5,262,522,[6] and 5,237,051,[7] as demonstrating that one skilled in the art would be "able to determine and define moderately stringent conditions based on the knowledge and skill at that time. All have claims that include the term 'moderate stringency.'" (Br. 12-13.) Appellants assert that the opinions in *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819 (Fed. Cir. 1988) and *Ex Parte Brian*, 118 USPQ 242, 245 (Bd. App. 1958), support their argument that the use of the criticized language in the claims of other patents is relevant to the issue of definiteness.

We first note, as did the Examiner, that the term "moderate stringency" only appears once in the Specification (*see, e.g.*, Answer 17). The Specification states:

> In particular, the present invention provides a DNA sequence selected from the group consisting of:
> (a) a cDNA sequence derived from the coding region of a native MORT-1 protein;

[3] Dower, U.S.Patent No. 4,968,607, issued November 6, 1990.
[4] Cerretti, U.S. Patent No. 5,171,675, issued December 15, 1992.
[5] Maliszewski, U.S. Patent No. 5,198,342, issued March 30, 1993.
[6] Gearing, U.S. Patent No. 5,262,522, issued November 16, 1993.
[7] Garbers, U.S. Patent No. 5,237,051, issued August 17, 1993.

> (b) DNA sequences capable of hybridization to a cDNA of (a) under *moderately stringent conditions* and which encode a biologically active FAS-R intracellular domain-binding protein; and
> (c) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a) and (b) and which encode a biologically active FAS-R intracellular domain-binding protein.

(Specification 8 (emphasis added).) We also note that Appellants do not appear to disagree with this assessment, as they do not argue that the term "moderate stringency" is defined in the Specification such as to make it definite (*see, e.g.*, Reply Br. 2-3).

Thus, the issue becomes does the term "moderate stringency" reasonably apprise those skilled in the art the scope of Appellants' claimed invention.

Appellants rely on Patent Nos. 5,026,636, 4,968,607; 5,171,675; 5,198,342; 5,262,522; and 5,237,051, as demonstrating that one skilled in the art would be able to determine and define moderately stringent conditions based on the knowledge and skill at the time of invention.

US Patent No. 5,026,636 admittedly uses the term "moderately stringent conditions" in the claims (*see, e.g.*, claim 39). The '636 patent, however, specifically defines "moderately stringent." The patent discloses:

> Additional embodiments of the invention relate to DNA molecules capable of hybridizing to the recombinant insert of the 6 kbp EcoRI fragment designated plasmid pMPN P1 under selected hybridization conditions, said molecules suitable for use as hybridization probes. For example, one embodiment is directed toward a DNA molecule capable of hybridizing to the recombinant insert of plasmid pMPN P1, obtainable from ATCC #67560 (pending) under moderately stringent hybridization conditions while another embodiment is directed

> toward a DNA molecule capable of hybridizing to the recombinant insert of plasmid pMPN P1, obtainable from ATCC #67560 under stringent hybridization conditions. *For the purposes of the present invention*, such conditions are described as *moderately stringent in that they allow detection of a nucleotide sequence at least 14 nucleotides in length having at least approximately 75% homology with the sequence of the nucleotide probe used.* Stringent hybridization conditions are defined as conditions wherein the probe detects nucleotide sequences at least 14 nucleotides in length having a homology greater than about 90%. The conditions necessary for hybridization of a particular probe to a particular nucleotide sequence having a specified degree of homology may be determined by referring to *Nucleic Acid Hybridization, A Practical Approach*, Hames and Higgins, eds., IRL Press, Oxford and Washington, 1985, or Wood, et al., PNAS, 82:1585-1588 (1985), both incorporated herein by reference.

('636 patent, Col. 4, ll. 37-65 (emphasis added).) As noted by the '636 patent, both *Nucleic Acid Hybridization, A Practical Approach* and Wood allow one to determine the proper moderate stringency conditions *given a specified degree of homology*. None of *Nucleic Acid Hybridisation, A Practical Approach*, Wood, or *Current Protocols in Molecular Biology,* however, specify that moderately stringent conditions requires a certain level of homology. And the instant Specification has also not defined "moderately stringent conditions" as related to any particular degree of homology.

Moreover, *Nucleic Acid Hybridisation, A Practical Approach*, provides support that "moderately stringent conditions" has no well defined meaning in the art. In discussing "stringency of hybridization," (p. 81), the reference talks about relaxed or permissive conditions to distinguish between distantly related members of a family of DNA-sequences, and the use of

stringent criterion to detect closely-related members (p. 82). There would appear to be a broad range between relaxed and stringent conditions that would read on moderate stringency conditions, and thus encompassing a much broader range than the 75% homology that Appellants would like us to adopt.[8]

US Patent Nos. 4,968,607; 5,171,675; 5,198,342; 5,262,522; and 5,237,051 also do not help Appellants. As noted by Appellants, those patents define the conditions of moderate stringency: '607 (50°C, 2 X SSC; column 10, lines 39-40); '675 (50°C, 2 X SSC; column 6, line 49); '342 (50°C, 2 X SSC; column 9, lines 54-55); '522 (50°C, 2 X SSC; column 15, lines 8-9); and '051 (60°C, 1 X SSC; column 5, lines 24-27) (Br. 12). The fact that the conditions are the same or similar, however, does not render the term "moderately stringent" definite, because, as Wood makes clear, the G-C content of the nucleotide strand makes "suitably stringent and selective hybridization conditions difficult to find for all" oligonucleotide probes (Wood p. 1585, col. 1). That finding is supported by *Current Protocols in Molecular Biology*, which teaches that "[i]f the aim is to identify sequences that are merely related, not identical to the probe . . . then it is useful to have an idea of the degree of mismatching that will be tolerated by a 'moderate-' or 'low-' stringency wash." (*Id.* at 2.10.11.) The reference notes that base composition and mismatch distribution can influence the actual change in the melting temperature, and that "trial and error" is the only alternative

[8] This finding that moderate stringency encompasses a broad range is supported by US Patent No. 7,244,563 B2 to Cahoon, filed November 4, 2002. The '563 teaches that "substantially similar" nucleic acid fragments are fragments that hybridize under moderately stringent condition (for example, 0.5xSSC, 0.1% SDS, 60°C) and are *45% identical* to a nucleic acid sequences of the invention (col. 7, ll. 48-59).

(*id.*). Thus, Wood and *Current Protocols in Molecular Biology* support that "moderately stringent" wash conditions can vary depending on the base content, how related the sequences are, and the distribution of the mismatches. Notably, neither reference assigns a percent homology of relatedness of DNA sequences that are obtained using moderately stringent hybridization conditions.

As to the case law cited by Appellants, *i.e.*, *Andrew Corp.* and *Ex Parte Brian*, we find that the facts of the instant appeal are distinguishable, and thus, do not find those cases to be dispositive on the issue before us.

In *Andrew Corp.*, the court found that the terms "substantially equal" and "closely approximate" were "ubiquitous in patent claims." 847 F.2d at 821. Thus, *Andrew Corp.* dealt with different claim language, and there was evidence that the ordinary artisan would understand that a certain amount of variation was expected. (*See id.* at 822). Moreover, *Andrew Corp.* was a patent infringement case, and in infringement cases, claims are entitled to a presumption of validity, whereas no such presumption attaches in prosecution of patent applications before the PTO. *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). "It is the PTO's duty to assure that the statutory requirements of patentability are met." (*Id.*) Our mandate is to give claims their broadest reasonable interpretation. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). "An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989).

In *Ex parte Brian*, the Board found that claims to a compound defined by their empirical formula and their physical and chemical characteristics coupled with their infra-red absorption spectra was not indefinite, and that method had been used in a "numerous" number of patents. 118 USPQ at 245. In the instant case, Appellants have not presented a single patent in which moderate stringency is used in the claims and not defined in the disclosure. In addition, the preponderance of the evidence of record, as discussed above, supports that the term "moderate stringency" can encompass a wide variety of nucleic acids of different length and different homology to the nucleic acid to which it is hybridized. *See, e.g., Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office); *In re Kollar*, 286 F.3d 1326, 1329 (Fed. Cir. 2002) ("The PTO bears the initial burden by establishing that a preponderance of the evidence establishes *prima facie*, facts supporting the conclusion that the claimed invention was on sale within the meaning of § 102(b).")

Appellants respond that the "examiner has not cited any reference to show that one of ordinary skill in the art would consider the term to be other than what applicants have established." Appellants cite *In re Barr*, 444 F.2d 588 (CCPA 1971) and MPEP § 2173.02 (which cites *In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999), to support the argument that the terms must be construed from the standpoint of the ordinary artisan, and that it is permissible to consider how similar language is defined and interpreted in other patents.

As noted above, the patents and the evidence cited by Appellants do not establish that moderate stringency has an art accepted meaning of being

75% homologous. Rather, evidence of record supports the Examiner's position that "moderate stringency" can in fact read on a wide variety of homologies, and thus, the scope of the claims is uncertain. Thus, finding that the term "moderately stringent" hybridization conditions in the instant case "does not conflict[ ] with the meaning given to identical terms in other patents from analogous arts," *Cortright*, 165 F.3d at 1358, as in each of the patents cited by Appellants, either the percent homology, or the moderately stringent conditions, are defined.

Appellants also assert that there are cases in which terms are found definite, even though the terms are not found in the specification, such as *Bancorp Services L.L.C. v. The Hartford Life Ins. Co.*, 359 F.2d 1367 1372 (Fed. Cir. 2004) (Reply Br. 3). That case, as noted by Appellants, found that the disputed term had a well recognized meaning (Reply Br. 3), which Appellants have not established in this case.

Thus, the rejection of claims 1-7, 11, and 14 under 35 U.S.C. § 112, second paragraph, is affirmed.

Written Description

Claims 1-7, 11, and 14 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Again, as Appellants did not argue the claims separately, we focus our analysis on representative claim 1.

According to the Examiner, "[d]ue to the indefinite language of "hybridization under moderately stringent conditions", which is a relative term, supra, a DNA sequence hybridizing under moderately stringent conditions with the DNA sequence encoding SEQ ID NO:2 encodes a

peptide or protein of any size, and unknown structure, wherein said peptide or protein does not have to share a substantial sequence homology with SEQ ID NO:2." (Answer 7). Thus, the Examiner asserts, a DNA sequence that may have the ability to hybridize to the cDNA encoding SEQ ID NO:2 under the undefined "moderately stringent conditions," does not define a structure of a DNA sequence that encodes an analog of the MORT-1 protein that binds to FAS-IC (*id.*).

The Examiner notes further that the Specification "does not describe structure of any of the claimed DNA sequences encoding a genus of analogs, other than the DNA sequence encoding SEQ ID NO:2, and its fragments consisting of the "death domain" consisting the amino acid sequence of residues 153 to 215 of SEQ ID NO:2, and the C-terminal amino acids 130-245 of SEQ ID NO:2." (*Id.* at 8.) The Examiner argues that the Specification does not disclose a correlation between the structure of the C-terminal amino acids 130-245 of SEQ ID NO:2 and binding to FAS-IC (*id.* at 9).

The Examiner concludes:

> The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions, which are critical to the structure and function of the genus claimed. There is no description, however, regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, no identifying characteristic or property of the instant genus of polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

> Since the disclosure fails to describe the common attributes or characteristics that identify members of the DNA sequences encoding a genus of analogs, and because the genus is highly variant, the disclosure of specific nucleotide sequences, the DNA sequence encoding SEQ ID NO:2 or its C-terminal amino acids 130-245 of SEQ ID NO:2 and the ability to screen, is insufficient to describe the DNA sequences encoding a genus of analogs. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the DNA sequence encoding a genus of analogs as broadly claimed. Thus, the claims and the specification do not meet the written description provisions of 35 USC 112, first paragraph, and one would conclude that Appellant did not have possession of the claimed DNA sequences encoding a genus of analogs at the time the invention was made.

(*Id.* at 10-11.)

The requirement for written description under the first paragraph of section 112 is separate and distinct from the enablement requirement of that paragraph. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Compliance with the written description requirement is a question of fact. *Id.*

Appellants argue that the Examiner has intertwined the written description analysis with the indefiniteness analysis (Reply Br. 5). If the claims are not adequately described, however, they cannot be supported by an adequate written description as required by the case law set forth above. For example, one cannot correlate function to structure when one does not know the meets and bounds of the structure. The rejection is therefore affirmed. In the event that prosecution is continued, we direct the Examiner's and Appellants' attention to the written description analysis in *Ex parte Kubin*, 83 USPQ2d 1410, 1415-17 (Bd. Pat. App. & Int. 2007).

Enablement

Claims 1-7, 11, and 14 stand rejected under 35 U.S.C. § 112, first paragraph, because "the specification, while being enabling for a DNA sequence encoding SEQ ID NO:2, or a fragment thereof comprising amino acids 130-245 of SEQ ID NO:2, does not reasonably provide enablement for 1) a DNA sequence encoding an analog of SEQ ID NO:2, which analog binds with the intracellular domain of the FAS ligand receptor (FAS-IC), which DNA sequence is capable of hybridizing to the cDNA encoding SEQ ID NO:2 under moderately stringent conditions, or 2) a DNA coding sequence consisting of a DNA sequence which encodes a fragment of said MORT- 1 protein which binds with FAS-IC. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims." (Answer 11-12.) We again focus our analysis on claim 1.

The Examiner asserts that given "the lack of adequate disclosure in the specification, and in view of the complex nature of the claimed invention, and little is known in the art about the claimed invention, one of skill in the art would be forced into undue experimentation to practice the claimed invention."

Enablement is a question of law, based on underlying findings of fact. *See, e.g., In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988). "When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled

by the description of the invention provided in the specification of the application." *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

"[T]o be enabling, the specification . . . must teach those skilled in the art how to make and use *the full scope of the claimed invention* without 'undue experimentation.'" *Wright*, 999 F.2d at 1561 (emphasis added), *quoted in Genentech, Inc. v. Novo Nordisk, A/S,* 108 F.3d 1361, 1365 (Fed. Cir. 1997). Thus, "there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed." *In re Vaeck*, 947 F.2d 488, 496 & n. 23 (Fed. Cir. 1991), *quoted in Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1372 (Fed. Cir. 1999).

"Patent protection is granted in return for an enabling disclosure . . . , not for vague intimations of general ideas that may or may not be workable." *Genentech*, 108 F.3d at 1366. "Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, *reasonable detail* must be provided in order to enable members of the public [skilled in the art] to understand and carry out the invention." *Id.* at 1366 (emphasis added).

As noted above, the claim limitation that the "DNA sequence is capable of hybridization to the cDNA encoding SEQ ID NO:2 under moderately stringent conditions" is indefinite. Thus, as Appellants have not adequately defined the invention, one of skill in the art could not make or use the full scope of the claimed isolated DNA molecules, and the rejection is affirmed.

CONCLUSION

In summary, we conclude that the claims are indefinite and thus do not meet the requirements of 35 U.S.C. § 112, second paragraph, and the rejection under 35 U.S.C. § 112, second paragraph, and the rejections under 35 U.S.C. § 112, first paragraph, are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED

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